UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/522,252	02/15/2006	Florence Guimberteau		8812

32042 7590 08/19/2008

PATTON BOGGS LLP
8484 WESTPARK DRIVE
SUITE 900
MCLEAN, VA 22102

EXAMINER	
EBRAHIM, NABILA G	

ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
08/19/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/522,252	GUIMBERTEAU ET AL.	
	Examiner	Art Unit	
	Nabila G. Ebrahim	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 May 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16,17 and 19-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16,17 and 19-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *05/01/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The receipt of Information Disclosure Statement dated 05/01/2008 and the amendments to the claims is acknowledged.

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 16, 17 and 19-31 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-13 of copending Application No. 10/522234.

'234 is drawn to microcapsules, each having a core which contains an active agent and a solubilizing agent, and surrounded by a coating made of two types of polymers, plasticizers and lubricants. The active agents are the same and the microcapsules have the same size. The amount of ingredient is the same and the structure of the microcapsule is also the same.

This is a provisional obviousness-type double patenting rejection.

3. Claims 16, 17 and 19-31 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-13 of copending Application No. 11/583940.

'940 is drawn to microcapsules, each having a core which contains an active agent and a solubilizing agent, and surrounded by a coating made of two types of polymers, plasticizers and lubricants. The active agents are the same and the microcapsules have the same size. The amount of ingredient is the same and the structure of the microcapsule is also the same.

This is a provisional obviousness-type double patenting rejection.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 16, 17, 19-26 and 28-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Mehta US 5084278 (Mehta). .

Mehta teaches microcapsule with a core wherein the core comprises an active agent and a diluent (corresponds to the solubilizing agent in the instant claims). The core is surrounded by a coating which comprises a film-forming polymer (abstract). preferred coating composition is a mixture comprised of at least about 5% of a high temperature film forming polymer and about 5% of a low temperature film forming polymer based on the total weight of polymer in the microcapsule coating (col. 4, lines 24+). A preferred high temperature film forming polymer can be ethyl cellulose (col. 5, line 21). The low temperature film forming polymer can be any of a group of plasticizers including glyceryl triacetate polyvinyl pyrrolidone (col. 5, lines 41+). The microcapsules are 0.25-1 mm in diameter (col. 2, lines 21-22). The

diluent added to the core material may be hydroxypropyl or hydroxypropyl methyl cellulose, polyvinyl alcohol, polyvinylpyrrolidone, and ethylcellulose among others (col. 8, lines 10+). Note that since the same polymers are used with the active agent in the core, it should be capable of increasing the solubility of the at least one active principle by more than 50% as required by instant claim 1. Mehta also discloses the use of lubricants such as magnesium stearate (col. 8, line 14). The microcapsules can be prepared to release the active agent in the intestine (col. 6, lines 33-34), the disclosure is understood as the coating polymer is not soluble in the stomach as required in the instant claims. The drugs that can be comprised in the core are antibiotics, and ibuprofen among others (col. 7, lines 48+). It is noted that since Mehta teaches the same microcapsule ingredients in the same structure and amounts, and since the mass fraction is calculated as:

Mass fraction (w_A) is the ratio of the mass of substance A to the total mass of a mixture. It is expected that Mehta's ingredient mass fraction would have the same value recited in the claims.

Regarding the release profile recited in amended claim 16, absent of evidence on the contrary, the burden is shifted to applicant to show that the microcapsules taught by Mehta would not exhibit the claimed properties. It is noted that products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). In the instant application, Mehta teaches the use of the same coating composition comprising the same ingredients, and in the same concentrations.

Thus Mehta remain anticipating instant claims 16-26 and 28-31.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 16-17, 19-31 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Mehta US 5084278, in view of Mulye US 6946146 (Mulye).

Mehta is relied upon for the reasons set forth hereinabove

Mehta does not explicitly teach the amount of the claimed lubricant surfactant.

Mulye teaches coating for sustained release pharmaceutical composition. The coating composition of the invention may be used to coat various cores or substrates containing the active ingredient such as tablets, spheroids (or beads), microspheres. The dosage form contains cores which contain the medicament or therapeutically active agent which is administered to a mammal. The coating layer may include a lubricant. Examples of suitable lubricants include calcium stearate, colloidal silicon dioxide, magnesium stearate, aluminum stearate, or a mixture of any two or more of the forgoing, and the like. If present, the lubricant is present in amounts ranging from about 0.01% to about 10% by dry weight of the coating (col. 8, lines 38+).

Regarding the new amendments to the claims, since Mehta used the same compounds in the invention, then the core should have the properties of the core is inherent.

Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the microcapsule of Mehta using a lubricant in an amount around the percentage disclosed by Mulye in the coating because Mehta teaches microcapsules having sustained/modified release profiles. The expected results would be an orally administered microcapsule having cores containing an active agent and a solubilizing compound and having a coating which comprises two kinds of polymers, one is a film forming and not soluble in the stomach and the other is water soluble, a plasticizer and a lubricant.

Response to Arguments

1. Applicant's arguments filed 5/13/2008 have been fully considered but they are not persuasive. Applicant argues that:

CLAIM REJECTIONS UNDER OBVIOUSNESS-TYPE DOUBLE PATENTING

- Applicant argues the two provisional obviousness double patenting rejections over applications 10/522234 and 11/583940 alleging that the two sets of claims do not recite the

subject matter of instant claim 16, however, applicant does not provide the reasons of why he thinks that the instant claims are not anticipated or obvious over the two sets of claims of applications 10/522234 and 11/583940.

REJECTIONS UNDER 35 U.S.C. § 102

- Applicant notes that Mehta pulled ethyl cellulose from a laundry list, where ethyl cellulose is used as a diluent in the core. This has no bearing on the present claims, because the invention is to use of ethyl cellulose as an element of the coating, and is not used in the core. Further, ethyl cellulose is not a solubilizing agent.

To respond: First, as a clarification, there was misplaced in the non-final office action the sentence is " Note that since the same polymers are used with the active agent in the core, it should be capable of increasing the solubility of the at least one active principle by more than 50% as required by instant claim 1". The office action states clearly the polymers that are used in the core and the sentence should follow the statement including these polymers. This inadvertent error has been corrected.

Mehta used hydroxypropyl or hydroxypropyl methyl cellulose, polyvinyl alcohol, polyvinylpyrrolidone, and ethylcellulose among others as diluents (col. 8, lines 10+) -see Office Action, page 4- these compounds though being used as diluents, they will accrue its solubilizing capabilities in Mehta's core. Same compounds have same properties. Regarding the laundry list alleged by applicant, it is noted that in claim 19, Applicant recites in claim 19 more than 20 kinds of solubilizing agents including generic compounds such as surfactants and hydrophilic derivatives of cellulose wherein these categories would form much longer laundry list if recited in species. It is clear that the possible different solubilizing agents are of a big number of compounds.

- There is no evidence in Mehta that use of ethyl cellulose in the core would work as to increase the solubility of the active principle. In fact, as the instant specification and claims state, ethyl cellulose is water-insoluble. To Applicant's knowledge, there is no evidence that ethyl cellulose would work as a solubilizing agent.

To respond: Mehta used other polymers in the core as diluents which are recited in instant claim 19 such as hydroxypropyl or hydroxypropyl methyl cellulose, polyvinyl alcohol, polyvinylpyrrolidone. A compound and its properties are not separable, the prior art clearly use the same polymers. It is not necessarily that the prior art recognizes each and every advantage that a compound can accrue from the use of the particular ingredient.

- Applicant submits that Mehta cannot anticipate the current claims because Mehta is so vague and obtuse that it is unclear which compounds are "high" or "low" temperature film forming polymers and how they are to be combined and/or used.

To respond: Mehta teaches microcapsule with a core wherein the core comprises an active agent and a diluent (corresponds to the solubilizing agent in the instant claims). The core is surrounded by a coating which comprises a film-forming polymer. The active agent is mixed with the same polymers such as polyvinyl alcohol, polyvinyl pyrrolidone and the coating is made from the same polymers such as ethylcellulose. Regarding Applicant allegation that Mehta is vague and the disclosure contains errors, it is noted that Mehta is not under current prosecution, but the current claims are.

REJECTION UNDER 35 U.S.C.§103

- Mulye does not cure the deficiency in Mehta as Mulye also does not teach a solubilizing agent in the core.

To respond: Mehta disclosed the same polymers recited in instant claim 19 which are the solubilizing agents. Mulye is relied upon for disclosing the lubricant surfactant such as calcium stearate, colloidal silicon dioxide, magnesium stearate, aluminum stearate, or a mixture.

1. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nabila G. Ebrahim whose telephone number is 571-272-8151. The examiner can normally be reached on 8:00AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nabila G Ebrahim/
Examiner, Art Unit 1618

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618